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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/916,937	07/27/2001	Paul Lubock	26684-1250	9292

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/916,937

Applicant(s)

LUBOCK ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-17, 21-26, 28-30, 32-39, 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 18-20, 27, 31 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed September 4, 2003. The Examiner acknowledges the amendments to claims 1-4, 18, 20, 31 and 40. Applicant indicates that claim 27 has also been amended, but claim 27 is listed as "withdrawn" in the pending claims and no amendment has been made to the claim. The Examiner further acknowledges the Applicants withdrawal of their claims to priority to the earlier filed applications. Claims 1-44 are pending, and claims 5-17, 21-26, 28-30, 32-39 and 41-44 have been withdrawn from consideration.

Claim Objections

2. Claim 1 is objected to because of the following informalities: in line 7, --a-- apparently should be inserted before "transverse". Appropriate correction is required.

3. Claim 40 is objected to because of the following informalities:

- a. In line 4, "a" apparently should read --said--.
- b. In line 7, "separate" apparently should read --separated--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3736

5. Claims 1-4, 18-20 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1, 4 and 18, inconsistent terminology used to define a claim limitation renders the claim indefinite, as it is unclear how many tissue securing members form the claimed device. Claim 1 recites the limitation "at least one tissue securing member" in line 4. However, the limitation "the tissue securing member" is recited in claim 1, lines 6-7 and claim 18, line 2; and the limitation "the securing member" is recited in claim 4, line 3. The subsequent recitations of the limitation render the claim indefinite because it is unclear whether the device includes only one securing member or if the device can include a plurality of securing members.

Regarding claim 40, inconsistent terminology used to define a claim limitation renders the claim indefinite, as it is unclear how many tissue securing members form the claimed device. Claim 40 recites the limitation "at least one tissue securing member" in line 3. However, the limitation "the tissue securing member" is recited in claim 40, lines 6-7. The subsequent recitations of the limitation render the claim indefinite because it is unclear whether the device includes only one securing member or if the device can include a plurality of securing members.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3736

7. Claims 1-4, 18, 19, 27, 31 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Mollenauer ('418). Mollenauer teaches elongated tissue removing devices for harvesting blood vessels. The devices include an elongate shaft **16** with at least one tissue securing member **15,43,55** on a distal shaft section; and a tissue expander or dilation device **23** on the elongate shaft proximal to the tissue securing region to facilitate removal of a tissue mass. The tissue expander **23** comprises an inflatable balloon **25** that is attached to the elongate shaft proximal of the region for securing a tissue mass. The distal tip of the shaft **16** is pointed, forming a cutting surface capable of penetrating tissue. The region for securing a tissue mass includes an anchoring member **15** formed by an elongate balloon **18,43** that is configured to deploy into tissue. The devices may be provided as a unit or as a plurality of elements in a kit that are assembled to form the device.

Allowable Subject Matter

8. Claim 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: No prior art of record teach or fairly suggest a tissue removal device including a shaft having a tissue securing region and a tissue expander/dilation device disposed on the shaft proximal to the tissue securing region, where the tissue securing region is formed by an elongated electrosurgical anchor element that is configured to deploy into tissue.

Response to Arguments

10. Applicant's arguments filed September 4, 2003 have been fully considered but they are not persuasive. Applicant contends that Mollenaurer does not disclose or suggest a device having a tissue expander which has an expanded configuration with greater transverse dimensions than the separated tissue which allows for the removal of a tissue mass through a tissue passageway leading to the separated tissue mass which has smaller transverse dimensions than the tissue mass itself. Claims 27, 31 and 40 do not claim that the dilation device has an expanded configuration with greater transverse dimensions than the separated tissue. Claims 1-4 and 18-20 recite that the tissue expander has an expanded configuration with a transverse dimension greater than the transverse dimensions of the separated tissue mass. There are no limitations in the aforementioned claims that recite that the tissue mass to be removed has a larger transverse dimension than the removal passageway. Since the tissue expanding balloon of Mollenauer has a larger transverse dimension than the harvested blood vessel for dilating a path in tissue in order to separate and mobilize the blood vessel from the surrounding tissue, Mollenauer reads on all of the limitations of the claims. As such, the rejections of claims 1-4, 18, 19, 27, 31 and 40 under 35 USC 102(b) as anticipated by Mollenauer are maintained.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Carroll ('458) teaches a minimally invasive surgical probe for tissue identification

Art Unit: 3736

and retrieval. Kieturakis ('282) teaches a surgical instrument and method for removing tissue from an endoscopic workspace. Graber et al. ('647) teach a tissue and organ extractor.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

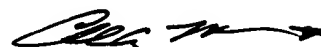
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Art Unit: 3736

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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January 9, 2004